

Laboratory Services

Tailored laboratory solutions for all pharmaceutical modalities from pre-clinical to post-approval phases of development. Alcami has the experience and expertise to develop appropriate controls for products manufactured in our facilities or to supplement externally manufactured programs with specialty studies to meet regulatory requirements.

Beyond expectations.



Alcami offers fully-integrated analytical method development, method validation and testing solutions for raw materials, API/BDS and Drug Product.

Built on a foundation of comprehensive analytical services for pharmaceuticals including biologics, our advanced laboratories and experienced scientists specialize in method development, validation, and testing. These services ensure product quality, compliance, and informed decision-making from early development to commercialization, supporting clients in delivering safe and effective products to market.

Supported Modalities

Small Molecule Peptides Proteins Oligonucleotides Cell & Gene Therapies

CAPABILITIES

Method Development, Optimization, Validation and Testing

Evaluation & Transfer, Inter-lab Qualifications

USP/NF/EP/JP/BP/ACS/FCC Method Verification and Routine Testing

API, Drug Product & Intermediates / In-Process Testing

Raw Material & Component, Release Testing

Stability Storage, Testing, & Trending

Stand-Alone and Manufacturing Support, Fixed Bid and FTE options

Comprehensive Microbiology

Structural Characterization and Impurity Identification

Extractables & Leachables

Elemental Impurities

High Potent, Hygroscopic, Photosensitive, Controlled Substance



ANALYTICAL DEVELOPMENT

Alcami's GMP analytical laboratories are arranged to maximize efficiency and deliver results - from the electronic laboratory notebook (ELN) data collection system to direct integration with formulation development, project management, and quality systems, we are equipped to meet your drug development needs.

Core capabilities:

Drug substance and drug product stability indicating assays

Related substances, chiral purity, elemental impurity, and residual solvent analysis

Dissolution testing with UV and HPLC backend

Preservative and stabilizing excipients assays

Phospholipid and fatty acid analysis

Impurity ID and Structural Characterization

Particle Size Analysis

Physical and structural chemistry

Remedial method validation/method lifecycle evaluation studies

Drug substance and reference standard material characterization

Reference standard qualification

Process validation support

Cleaning method verification

Drug product comparator studies

Material contact studies

In-use and administration set compatibility studies

Extractables and leachables studies

Nitrosamine Testing

API polymorph screening

API salt form selection

API structural chemistry

FORMULATION DEVELOPMENT

Alcami's formulation development team proactively guides your development program every step of the way – from Compound to Clinic. Our team is adept at solving challenging formulations for new chemical entities (NCEs) and developing high-performance dose forms to meet today's consumer needs. We offer early-phase accelerated programs for NCEs and generic drug development for human and veterinary applications (ANDAs and ANADAs).

Core capabilities:

Accelerated first-in-human clinical trial materials

Bioavailability enhancement

Clinical formulation development

Commercial dosage form design

Drug candidate selection

Drug excipient compatibility studies

Injectable prototype development

Matching placebo development

Drug product lifecycle management

Drug substance pre-formulation studies

Pediatric formulation development

Pharmaceutical process development

Powders for reconstitution

Preclinical formulation development

Quality by design (QbD)

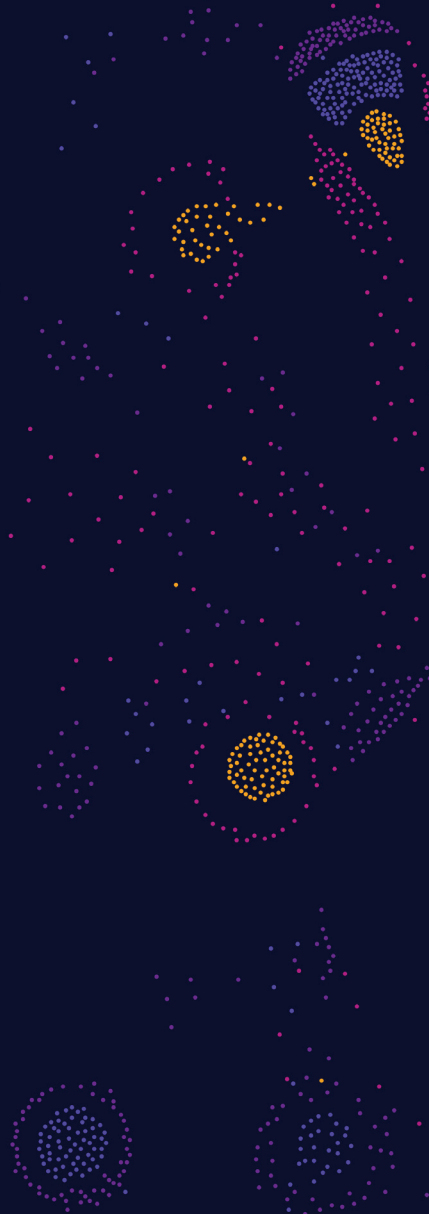
Solid oral dose prototype development

Technology transfer and process scale-up



alcami.[®]

Beyond expectations.



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Drug Product Manufacturing
Laboratory Services
Pharma Storage & Services

Charleston, SC • Wilmington, NC
RTP, NC • St Louis, MO
New England • Reno, NV